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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 899,917	07.09.2001	Henrik S. Olsen	1488.0440003	5233

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HUMAN GENOME SCIENCES INC
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EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07.02.2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/899,917

Applicant(s)

OLSEN ET AL.

Examiner

Hope A. Robinson

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 17-116 is/are pending in the application.
- 4a) Of the above claim(s) 29,37,48,54,60,75,82,91,100,108 and 115 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 17-28,30-36,38-47,49-53,55-59,61-74,76-81,83-90,92-99,101-107,109-114 and 116 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's response to the Office Action mailed January 14, 2003 in Paper No. 12 on April 14, 2003 is acknowledged

Claim Disposition

2. Claims 39-44, 50, 56, 93, 102, 104, 110 and 111 have been amended. Claims 17-116 are pending. Claims 17-28, 30-36, 38-47, 49-53, 55-59, 61-74, 76-81, 83-90 and 92-99 are under examination.

3. The objection to the Priority Data has been withdrawn as the specification has been amended.

The objected and the Information Disclosure Statement have been withdrawn as an English equivalent to the foreign document was found and considered.

The rejection under 35 U.S.C. 101 Utility has been withdrawn as the specification has an asserted utilities.

The rejection under 35 U.S.C. 112, first paragraph enablement has been withdrawn as the Honjo et al. teach a protein "OHP106" that is 100% identical to the claimed protein that is useful for treatment of bacterial and viral infection with cytokine activity and activities such as cell proliferation/differentiation, immunostimulation/suppression, control of haematopoiesis and tissue formation/repair.

The rejection under 35 U.S.C. 112, second paragraph has been withdrawn because claims 102 and 104 (regarding "nucleic acid encoded by the cDNA") have been amended; claims 20-25, 32, 33, 62 (regarding "(-)" as this represents the signal sequence) and claims 39-44, 50, 56, 62, 93, 102, 104, 110 and 111 (regarding "ATCC as a trademark") have been reconsidered.

4. The following grounds of rejection are applicable:

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 17-28, 30-36, 38-47, 49-53, 55-59, 61-74, 76-81, 83-90 and 92-99 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The present application on page 20 refers to the invention as "relating to a Human Oncogene Induced Secreted Protein I (HOIPS) encoded by the deposited cDNA clone (ATCC No: 97825). It is also stated on page 8, lines 13-16 that the HOIPS I protein is about 45% identical to about 64% similar to

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chicken MD-1 protein. However, the claims are directed to an isolated protein comprising an amino acid sequence at least 90% identical to amino acids 1 to 142 of SEQ ID NO: 2 (see claim 17, for example). The claims are also directed to the amino acid sequence bearing one to five conservative amino acid substitutions and a sequence that is 95% identical to the amino acid sequence encoded by the cDNA in ATCC Deposit No. 97825 and methods of producing the claimed protein. However, the specification lacks adequate written description with regard to the deposit information. It is noted that throughout the specification, see for example page 7, lines 7-8 it is disclosed that the deposit was made at ATCC on December 16, 1996 and the address of ATCC is provided, however, the specification does not indicate whether the clones are deposited under the Budapest Treaty and there is no disclosure as to whether the clones are readily available thus is considered insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met. Without publicly available deposit information one of skill in the art could not be assured of the ability to practice the invention as claimed.

If deposits have not been made under the Budapest Treaty, then in order to certify that the deposits meet the criteria set forth in 37 CFR 1.801-1.809, applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(A) During the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

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(B) All restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(C) The deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(D) The deposits were viable at the time of deposit;

(E) The deposits will be replaced if they should ever become non-viable.

This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each member State. Amendment of the specification to disclose the date of the deposit and the complete name and address of the depository is required.

For further information concerning deposit practice, applicants attention is directed to *In re Lundak* 773 F 2d 1216 227 USPQ CAFC and 37 CFR 1.801-1.809.

The claims are directed to an isolated protein comprising an amino acid sequence at least 90% identical to amino acid residues 1 to 142 of SEQ ID NO: 2 and the claims have no limitations to the function of the protein. Therefore, these claims are drawn to a large variable genus of polypeptides with unknown activity or inactive variants. In addition, the unspecified variants have not been adequately described in the instant specification as no special features or characteristics for the variants are provided. Therefore, the specification fails to describe representative species by identifying characteristics or structural properties other than having sequence similarity to SEQ ID NO: 2. Given this lack of description of the representative species

encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize that applicants were in possession of the invention as claimed.

The specification provides no measurable end point to allow one of skill in the art to be able to determine if a polypeptide that is in possession of another, and having at least 90% identity to SEQ ID NO:2, for example, falls within the description of the polypeptides as claimed. The specification does not describe polynucleotides encoding polypeptides having at least 90% identity to SEQ ID NO: 2 and do not have the asserted function, for example. The claims must recite a specific, measurable activity such that one can recognize a polypeptide as that claimed, or a fragment thereof. In order to make an accurate assessment of the modifications encompassed by these claims and to determine the function of the encoded protein fragment would require undue experimentation. Thus, functional language needs to be in the claim to provide a measurable end point. Therefore, at the time the application was filed, would not have taught one skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.

6. The amendment filed April 14, 2003 in Paper No.12 has been considered. Note that the rejections and objections of record have been withdrawn. The arguments presented on pages 5-12 have been considered, however, are moot as the rejections have been withdrawn. Note that new grounds of rejections have been instituted under 35 U.S.C. 112, first paragraph Written Description. The Patent and Trademark Office

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Written Description guidelines state that " An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e. complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics". Thus, applicant needs to amend the claims to recite the functional language disclosed in the instant specification.

Conclusion

7. No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703) 308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 6:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, Ph.D., can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you

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choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS 

Patent Examiner



CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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